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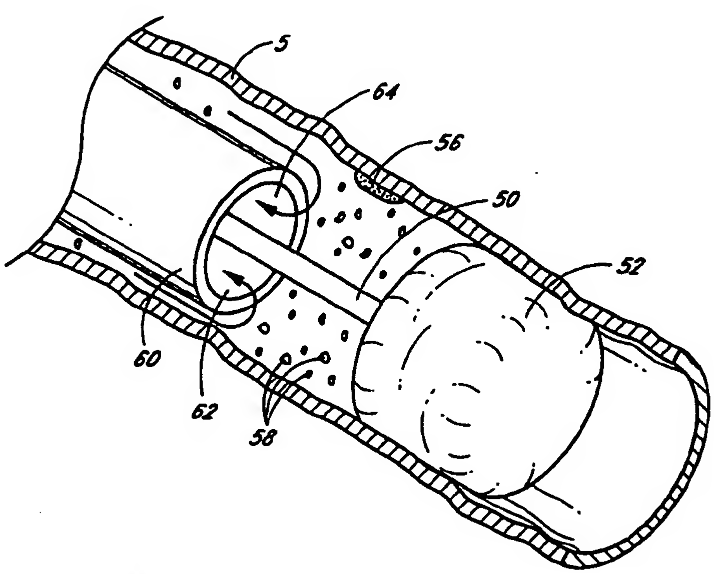

(57) Abstract

Catheters and method for the treatment of stenosis or an occlusion (56) in a blood vessel (5) in which an occlusive device (52) is first delivered and the occlusive device (52) activated at a site distal to the occlusion (56) to at least partially occlude the vessel (5) and create a working space surrounding the occlusion (56). A therapy catheter is then introduced to treat the occlusion (56) and a debris removal device (60) is delivered to aspirate debris (58) from the vessel (5). The need for a separate irrigation catheter and irrigation fluid is eliminated, which allows the procedure to be performed quickly and efficiently. The catheters and method are especially useful in the removal of occlusion from saphenous vein grafts, the coronary and carotid arteries, arteries above the aortic arch and vessels of similar size and pressure.

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INTRAVASCULAR ASPIRATION SYSTEM

Background of the Invention

Field of the Invention

The present invention relates to intravascular catheters and an improved method for aspirating emboli, thrombi, and other types of particles from the human arterial or venous system. The catheters and method are particularly well suited for treating stenoses or occlusions within saphenous vein grafts, coronary arteries, arteries above the aortic arch such as the carotid arteries, and similar vessels.

Description of the Related Art

Human blood vessels often become occluded or completely blocked by plaque, thrombi, other deposits, emboli or other substances, which reduce the blood carrying capacity of the vessel. Should the blockage occur at a critical place in the circulatory system, serious and permanent injury, or even death, can occur. To prevent this, some form of medical intervention is usually performed when significant occlusion is detected.

Coronary heart disease is an extremely common disorder in developed countries, and is the leading cause of death in the U.S. Damage to or malfunction of the heart is caused by narrowing or blockage of the coronary arteries (atherosclerosis) that supply blood to the heart. The coronary arteries are first narrowed and may eventually be completely blocked by plaque, and may further be complicated by the formation of thrombi (blood clots) on the roughened surfaces of the plaques. Myocardial infarction can result from atherosclerosis, especially from an occlusive or near occlusive thrombi overlying or adjacent to the atherosclerotic plaque, leading to death of portions of the heart muscle. Thrombi and emboli also often result from myocardial infarction, and these clots can block the coronary arteries, or can migrate further downstream, causing additional complications.

Various types of intervention techniques have been developed which facilitate the reduction or removal of the blockage in the blood vessel, allowing increased blood flow through the vessel. One technique for treating stenosis or occlusion of a blood vessel is balloon angioplasty. A balloon catheter is inserted into the narrowed or blocked area, and the balloon is inflated to expand the constricted area. In many cases, near normal blood flow is restored. It can be difficult, however, to treat plaque deposits and thrombi in the coronary arteries, because the coronary arteries are small, which makes accessing them with commonly used catheters difficult.

Other types of intervention include atherectomy, deployment of stents, introduction of specific medication by infusion, and bypass surgery. Each of these methods are not without the risk of embolism caused by the dislodgement of the blocking material which then moves downstream. In addition, the size of the blocked vessel may limit percutaneous access to the vessel.

In coronary bypass surgery, a more costly and invasive form of intervention, a section of a vein, usually the saphenous vein taken from the leg, is used to form a connection between the aorta and the coronary artery distal to the obstruction. Over time, however, the saphenous vein graft may itself become diseased, stenosed, or occluded, similar to the bypassed vessel. Atherosclerotic plaque in saphenous vein grafts tends to be more friable and less fibrocalcific than its counterpart in native coronary arteries.

Diffusely diseased old saphenous vein grafts with friable atherosclerotic lesions and thrombi have therefore been associated with iatrogenic distal embolic debris. Balloon dilatation of saphenous vein grafts is more likely to produce symptomatic embolization than dilatation of the coronary arteries, not only because of the difference in the plaque but also because vein grafts and their atheromatous plaques are generally larger than the coronary arteries to which they are anastomosed. Once the plaque and thrombi are dislodged from the vein, they can move downstream, completely blocking another portion of the coronary artery and causing myocardial infarction. In fact, coronary embolization as a complication of balloon angioplasty of saphenous vein grafts is higher than that in balloon angioplasty of native coronary arteries. Therefore, balloon angioplasty of vein grafts is performed with the realization that involvement by friable atherosclerosis is likely and that atheroembolization represents a significant risk.

Because of these complications and high recurrence rates, old diffusely diseased saphenous vein grafts have been considered contraindications for angioplasty and atherectomy, severely limiting the options for minimally invasive treatment. However, some diffusely diseased or occluded saphenous vein grafts may be associated with acute ischemic syndromes, necessitating some form of intervention.

There is therefore a need for improved intravascular catheters and methods of treatment for occluded vessels such as saphenous vein grafts and the smaller coronary arteries which decrease the risks to the patient.

Summary of the Invention

In a preferred embodiment, the present invention provides catheters and a method for removing plaque, thrombi, emboli and other types of obstructions or occlusions from blood vessels having an inlet fluid pressure of at least 0.2 psi.

A combination of catheters are used as a system to remove occlusions from blood vessels. The method includes the use of a single occlusive device such as a balloon or filter to create a working space around the obstruction, a therapy catheter to treat the obstruction, and a source of aspiration to remove the debris created by the therapy. By utilizing the fluid pressure and flow within the blood vessel, this method eliminates the need for a separate irrigation catheter and irrigation fluid. The catheter system allows for the removal of occlusions more rapidly than known methods. Speed is essential in such procedures, since blood flow is significantly decreased or stopped during the time the vessel is occluded. The speed with which normal blood flow is restored is more critical in main vessels which supply blood to collateral vessels. The system allows for the removal of occlusions from saphenous vein grafts, coronary arteries, arteries above the aortic arch such as the carotid arteries, and blood vessels of similar pressure. The minimally invasive treatment can be provided at low cost and at relatively low risk to the patient.

In accordance with one aspect of the present invention, there is provided a kit comprising a combination of a catheter bearing an occlusive device, a therapy catheter, and an aspiration catheter. These catheters are all moveable with respect to one another and independently manipulatable. The catheters are preferably used in the removal of occlusions in saphenous vein grafts. The catheter bearing an occlusive device preferably comprises an elongated tubular body, an inflatable balloon mounted on the distal end the tubular body, a core-wire joined to the distal end of the tubular body, and a coil member disposed about the core-wire. The aspiration catheter preferably

comprises an elongate hollow shaft, a distal tip adapted for aspiration therethrough, and a proximal end adapted for connection with a source of negative pressure.

In accordance with another aspect of the present invention, there is provided a method for the treatment of a stenosis or an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi. The blood vessel can be a saphenous vein graft, a coronary artery, a blood vessel above the aortic arch, or any other vessel with a fluid flow rate of at least about 10 cc per minute, and more preferably, about 60 to 80 cc per minute. This flow rate is needed to provide adequate irrigation fluid, which allows for substantially complete aspiration of the area surrounding the occlusion in a very short period of time. Using this combination of irrigation provided from the blood flow into the vessel and aspiration, it has been found that aspiration of debris and fluid within the working area can occur in less than 3 seconds, but can also continue for 10 to 20 seconds or longer, until the procedure is completed. Thus, the physician can quickly and efficiently clear the debris from the area and restore normal blood flow through the vessel.

The method comprises first inserting a catheter or guidewire having an occlusive device at its distal end into the blood vessel, until it is distal to the stenosis or occlusion. It is to be understood that the stenosis or occlusion could be in a discrete location or diffused within the vessel. Therefore, although placement of the occlusive device is said to be distal to the stenosis or occlusion to be treated, portions of the diffuse stenosis or occlusion may remain distal to the occlusive device.

Once in place, the occlusive device is activated to substantially or completely occlude the vessel distal to the existing stenosis or occlusion and to create a working area surrounding the stenosis or occlusion. A therapy catheter is then inserted into the blood vessel until it reaches the stenosis or occlusion, and a desired therapy is performed on the stenosis or occlusion. The fluid inlet pressure within the vessel prevents any particles produced during therapy from flowing against the pressure and out of the working area, thus localizing the particles for aspiration. The therapy catheter is removed, and the distal end of an aspiration catheter or other device which creates an area of turbulence and uses negative pressure to aspirate fluid and debris is delivered into the vessel with the preferred placement being at the working area in a position just proximal to the occlusive device. Fluid is aspirated from the working area inside the vessel preferably proximal to the occlusive device to remove debris, while the fluid pressure within the vessel provides irrigation fluid within the working area. This aspiration creates a fluid flow within the working area, and provides a flow of irrigation fluid into the area. It is this combination of irrigation and aspiration that allows for very fast and efficient removal of debris. Once aspiration is complete, the aspiration catheter or similar device is removed and the occlusive device deactivated. Finally, the catheter or guidewire is removed from the vessel as well.

The insertion step can include the step of inserting the proximal end of the guidewire into the hollow lumen inside the aspiration catheter and advancing the aspiration catheter over the guidewire. This is commonly known as "over-the-wire" insertion. Alternatively, the proximal end of the guidewire can be inserted into a separate guidewire lumen on the aspiration catheter. Only a short portion of the aspiration catheter, as little as 5 cm, rides over the guidewire as the catheter is advanced. This is known as a single operator system, since, unlike the over-

the-wire systems, a second operator is not required to hold the long guidewire while the catheter is inserted into the patient; a single user alone can deliver the catheter over the guidewire in this system.

The distal end of the aspiration catheter or similar device is preferably slidably inserted into the vessel, preferably as close to the proximal side of the occlusive device as possible. Thereafter, the aspiration catheter should be pulled back by the operator, such that the distal tip slides proximal to the occlusive device. Thus, while the distal tip of the aspiration catheter is preferably initially at a position no more than about 5 cm proximal to the occlusive device, the operator then slides the aspiration catheter back, increasing the distance between the distal tip and the occlusive device. Aspiration can therefore occur anywhere between about 0 to 20 cm proximal to the occlusive device. The irrigation fluid supplied by the proximal portion of the blood vessel will move any particles or debris from a position proximal to the distal end of the aspiration catheter, thus allowing them to be aspirated. If a particle, however, is too far distal to the tip of the aspiration catheter, the irrigation fluid will tend to keep it there and not allow it to aspirated from the vessel. The tip of the aspiration catheter can therefore be slidably advanced in a distal direction again if desired, to ensure complete removal of debris. Once aspiration has begun, additional blood will flow into the area, creating turbulence and also allowing for the removal of debris.

If desired, a guide catheter can first be inserted into the patient's body to aid in the insertion of the guidewire and catheters. The guide catheter can be used to provide aspiration in place of the aspiration catheter if desired. The guide catheter is then removed following completion of the procedure.

In accordance with another aspect of the present invention, there is provided a method for the treatment of a stenosis or an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, and a fluid flow rate of at least about 10 cc per minute, and more preferably, about 60 to 80 cc per minute. The method comprises the steps of inserting a guidewire or catheter having an occlusive device on its distal end into the blood vessel, until the occlusive device is distal to the stenosis or occlusion. The occlusive device is activated to substantially occlude the vessel distal to the existing stenosis or occlusion and create a working area surrounding the stenosis or occlusion. A therapy catheter is then inserted into the lumen of an aspiration catheter or similar device, and the therapy catheter and the aspiration catheter are simultaneously delivered into the blood vessel until they reach the stenosis or occlusion. Therapy is performed to eliminate the occlusion, and the fluid pressure within the vessel acts to prevent any particles produced during therapy from flowing against the pressure and out of the working area. When therapy is complete, the therapy catheter is removed while the aspiration catheter remains, and fluid inside the working area is aspirated to remove the particles while the fluid pressure provides irrigation fluid within the working area. When aspiration is complete, the aspiration catheter or similar device is removed and the occlusive device is deactivated. The guidewire or catheter is also then removed.

In accordance with yet another aspect of the present invention, there is provided a method for the treatment of a stenosis or an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, and a fluid flow rate of at least about 10 cc per minute. The method comprises inserting an occlusive device into the vessel until the occlusive device is distal to the stenosis or occlusion. The device can be attached to the distal end of a catheter or guidewire. The device is actuated to occlude the vessels distal to the existing stenosis or occlusion and

create a working area surrounding the stenosis or occlusion. The fluid pressure within the vessel prevents any particles dislodged during insertion of the guidewire or catheter from flowing against the pressure and out of the working area. The distal end of an aspiration catheter or similar device is inserted to a position just proximal to the occlusive device, and fluid from the working area inside the vessel just proximal the occlusive device is aspirated. This will remove the stenosis or occlusion and any free particles while the fluid pressure provides irrigation fluid within the area. When aspiration is complete, the aspiration catheter is removed and the occlusive device deactivated. The guidewire or catheter is then removed.

Accordingly, the present invention provides for very fast and efficient aspiration of the working area surrounding the occlusion in a blood vessel. The patient's own blood provides the irrigation fluid, thereby eliminating the need for a separate irrigation catheter and supply of irrigation fluid. By reducing the number of devices needed to be inserted into the patient, the present invention reduces the amount of time required to complete the procedure, and allows the physician to restore normal blood flow in the vessel in a very short period of time.

Brief Description of the Drawings

FIGURE 1 is a perspective view of a human heart showing a saphenous vein graft used to bypass a portion of the coronary arteries.

FIGURE 2 is a side view of an over-the-wire aspiration catheter in accordance with the present invention.

FIGURE 3 is a cross section of the aspiration catheter of FIGURE 2, taken along line 3-3 in FIGURE 2.

FIGURE 4 is a cross section of the aspiration catheter of FIGURE 2 showing a guide wire over which the aspiration catheter rides.

FIGURE 5 is a side view of a single operator type aspiration catheter in accordance with the present invention.

FIGURE 6 is a cross section of the proximal end of the aspiration catheter of FIGURE 5, taken along line 6-6 of FIGURE 5.

FIGURE 7 is a cross section of the distal end of the aspiration catheter of FIGURE 5, taken along line 7-7 of FIGURE 5.

FIGURES 8A-C are side views of the various embodiments of the distal end of the aspiration catheter of the present invention.

FIGURE 9 is a perspective view of an over-the-wire aspiration catheter and guidewire inserted into a saphenous vein graft in accordance with the present invention, with the vein graft shown partially cut away.

FIGURE 10 is a schematic view of a catheter apparatus for use in the method of the present invention;

FIGURE 11 is a schematic cross-sectional view of a distal portion of the catheter apparatus shown in FIGURE 10.

Detailed Description of the Preferred Embodiment

In a preferred embodiment, the present invention provides catheters and a method for aspirating plaque, thrombi, emboli and other types of obstructions or occlusions from blood vessels having an inlet fluid pressure of at least 0.2 psi, such as saphenous vein grafts. The catheters and method are adapted for use in the treatment of

a stenosis or an occlusion in a blood vessel in which the stenosis or occlusion has a length and a width or thickness which at least partially occludes the vessel's lumen. The catheters and method of the present invention are effective in treating both partial and complete occlusions of the blood vessels. It is to be understood that "occlusion" as used herein, includes both complete and partial occlusions, stenoses, emboli, thrombi, plaque, and any other substance which at least partially occludes the lumen of the blood vessel.

The catheter system provides aspiration without the need for a separate irrigation catheter and irrigation fluid. In the context of removing plaque, thrombi or other blockages from blood vessels, it has heretofore been proposed that an isolated "chamber" surrounding the occlusion be created prior to attempting treatment, and that separate irrigation fluid be provided through an irrigation catheter to the chamber. It has been surprisingly discovered that isolation of the occlusion is not required, and that the occlusion can be successfully removed without the need for delivery of a separate irrigation catheter and irrigation fluid in those vessels where certain pressure and fluid flow conditions exist, such as saphenous vein grafts, coronary arteries, carotid arteries and other vessels.

In non-bifurcated areas of the blood vessels, it has been discovered that fluid from the collateral vessels or from the proximal portion of the same vessel acts as an infusion source. One can therefore occlude only the distal portion of the vessel to create a working area surrounding the occlusion and allow blood to flow from the proximal portion of the vessel into the working area. The working area surrounding the occlusion is aspirated through the guiding catheter or aspiration catheter. It should be noted that, as used herein, "proximal" refers to the portion of the apparatus closest to the end which remains outside the patient's body, and "distal" refers to the portion closest to the end inserted into the patient's body.

Preferably, the catheters and method of the present invention are used in any vessel of the body where the pressure is at least 0.2 psi, and more preferably, is about 1.2 psi, with a flow rate of at least 10 cc per minute. The catheters and method are preferably used in the removal of occlusions from saphenous vein grafts, coronary and carotid arteries, and vessels having similar pressures and flow where a suitable working area can be created. A saphenous vein graft is depicted in FIGURE 1. The graft 2 is used to bypass one of the occluded coronary arteries 4, and connects the aorta 6 to the coronary artery at a location distal the occlusion 8. Although the present invention will be described in connection with a saphenous vein graft, it should be understood that this application is merely exemplary, and the catheters and method can be used in other blood vessels as well.

Apparatus Used

To remove occlusions from the blood vessels in accordance with preferred embodiments of the present invention, a guide catheter having a single lumen is first introduced into the patient's vasculature through an incision made in the femoral artery in the groin and used to guide the insertion of other catheters and devices to the desired site. Following insertion of the guide catheter, an occlusive device is delivered to a position distal the occlusion. For example, a second catheter having an occlusive device, such as an inflatable balloon, filter, expandable braid or other mechanical occlusive device, attached at its distal end is inserted through the guide catheter and past the site of the occlusion. The occlusive device should be capable of preventing the migration of particles and debris from the working area, either through total or partial occlusion of the vessel. Note that the occlusion of the vessel need

not be complete. Substantial occlusion of the vessel can be sufficient for purposes of the present invention. The catheter should be sized so as to be slidable with respect to the therapy and aspiration catheters inserted over the catheter. The catheter is preferably made of metal such as stainless steel or nitinol, plastics, or composites. A guidewire having an occlusive device on its distal end is also suitable for use in the present method. The method of the present invention can be effectively carried out using a number of guidewires or catheters that perform the function of occluding the vessel and allowing for the slidable insertion of various other catheters and devices. The term "catheter" as used herein is therefore intended to include both guidewires and catheters with these desired characteristics.

A preferred catheter for use in the present invention is illustrated in FIGURES 10 and 11. The catheter apparatus 110 is generally comprised of four communicating members including an elongated tubular member 114, an inflatable balloon member 116, a core-wire member 120 and a coil member 122. The catheter apparatus 110 is preferably provided with an outer coating of a lubricous material, such as TEFLON.

The body member 114 of the catheter apparatus 110 is in the form of hypotubing and is provided with proximal and distal ends 114A and 114B as well as an inner lumen 115 extending along the tubular member 114. The balloon member 116 is coaxially mounted on the distal end 114B of the tubular member 114 by suitable adhesives 119 at a proximal end 116A and a distal end 116B of the balloon member 116 as in the manner shown in FIGURE 11. The core-wire member 120 of the catheter 110 may be comprised of a flexible wire 120. The flexible wire 120 is joined by soldering or brazing at a proximal end 120A of the flexible wire 120 to the distal end 114B of the tubular member 114 as in the manner show in FIGURE 11.

Preferably, the proximal end 120A of the flexible wire 120 has a transverse cross sectional area substantially less than the smallest transverse cross-sectional area of the inner lumen 115 of the tubular member 114. In the preferred embodiment, the flexible wire 120 tapers in the distal end 120B to smaller diameters to provide greater flexibility to the flexible wire 120. However, the flexible wire may be in the form of a solid rod or a helical coil or wire or combinations thereof.

As shown in FIGURE 11, the distal end 120B of the flexible wire 120 is secured to a rounded plug 118 of solder or braze at the distal end 122B of the coil member 122. The coil member 122 of the catheter 110 may be comprised of a helical coil 122. The coil member 122 is coaxially disposed about the flexible wire 120, and is secured to the flexible wire 120 by soldering or brazing at about the proximal end 120A of the flexible wire 120 as in the manner shown in FIGURE 11.

The balloon member 116 is preferably a compliant balloon formed of a suitable elastic material such as a latex or the like. The flexible coil 122 is preferably formed of a wire of platinum based alloys. The flexible core-wire 120 and the tubular member 114 are preferably formed of a nickel-titanium alloy.

Alternatively, the catheter for use in the present invention can be configured so as to allow for aspiration through the catheter, thus eliminating the need for a separate aspiration catheter. In this embodiment, the catheter has a long hollow shaft, having an outer diameter of less than about .038", and preferably about .025" to about .035". The inner diameter or lumen of the shaft is about .020" to about .030". Aspiration occurs through the inner

diameter of the catheter. The catheter has an occlusive device attached to its distal end. The occlusive device is preferably a mechanical device such as a self-expanding braid or coil which acts as a filter, preventing particles from moving downstream. The catheter shaft further comprises at least one opening, and preferably several openings located just proximal to the occlusive device, which allow for aspiration. The proximal end of the catheter is adapted to allow a source of negative pressure to be attached, such that it is in fluid communication with the inner lumen.

Once the guiding catheter and catheter have been properly positioned inside the vessel, the occlusive device at the distal end of the catheter is actuated to occlude the vessel distal to the existing occlusion to create a working area. A therapy catheter then is delivered to the site of the occlusion. The term "therapy catheter" is meant to include any of a number of known devices used to treat an occluded vessel. For example, a catheter carrying an inflatable balloon for use in balloon angioplasty can be delivered to dilate the occlusion. Thermal balloon angioplasty includes the use of heat to "mold" the vessel to the size and shape of the angioplasty balloon. Similarly, an intravascular stent can be delivered via a balloon catheter and deployed at the site of the occlusion to keep the vessel open. Cutting, shaving, scraping or pulverizing devices can be delivered to excise the occlusion in a procedure known as atherectomy. A laser or ultrasound device can also be delivered and used to ablate plaque in the vessel. Various thrombolytic or other types of drugs can be delivered locally in high concentrations to the site of the occlusion. It is also possible to deliver various chemical substances or enzymes via a catheter to the site of the stenosis to dissolve the obstruction. The term "therapy catheter" encompasses these and similar devices.

After the therapy has been performed and the stenosis has been removed using any of the methods and apparatus described above, the working area is aspirated to remove fluid and debris. Aspiration can be provided through the guide catheter if desired. A source of negative pressure is attached at the proximal end of the guide catheter, and fluid and debris are aspirated through the guide catheter's main lumen. Alternatively, an aspiration catheter or similar debris removing device is delivered to the working area to remove particles and any other debris. The term "aspiration catheter" includes any device which creates an area of fluid turbulence and uses negative pressure to aspirate fluid and debris, and includes thrombectomy catheters, rheolitic devices and those devices which create a venturi effect within the vessel. Thus, it is possible that a single catheter is used as both the therapy catheter and the aspiration catheter. It should be noted that any particles which break free during therapy and aspiration procedures will be kept at the site of the procedure within the working area by the occlusive device occluding the distal portion of the vessel in combination with the blood pressure coming from the proximal portion of the vessel. The debris is prevented from migrating elsewhere, and remains localized for removal by aspiration.

An aspiration catheter particularly suited for use with the method of the present invention is illustrated in FIGURE 2. The catheter 10 includes an adaptor 14 and a seal 16 at its proximal end. The catheter 10 further includes an aspiration port 18 to which a source of negative pressure is attached. The aspiration catheter further comprises a long hollow shaft 20 having a distal end 22. The distal tip 22 can include a radiopaque marker to aid in locating the tip 22 during insertion into the patient, and is preferably soft to prevent damage to the patient's vasculature.

The aspiration catheter illustrated in FIGURE 2 is an over-the-wire catheter. As seen in FIGURE 3, the catheter shaft 20 is hollow. During insertion of the aspiration catheter 10, the proximal end of a guidewire 26 is inserted into the distal end of the aspiration catheter 22, and the aspiration catheter 10 is slidably advanced over the guidewire 26, which is positioned inside the hollow lumen 24 of the aspiration catheter 10. The position of the guidewire 26 relative to the shaft 20 of the aspiration catheter 10 is illustrated in FIGURE 4, but of course can vary. For this type of aspiration catheter 10, a very long guidewire 26, generally around 300 cm in length, is used to facilitate the insertion of the aspiration catheter 10 over the guidewire 26.

Alternatively, the aspiration catheter 30 can be of a single operator design, as illustrated in FIGURES 5-7. The catheter 30 has an adaptor 32 and an aspiration port 34 at its proximal end. Like the over-the-wire aspiration catheter 10, the single operator aspiration catheter 30 further comprises a long hollow shaft 36 having a distal end 38. The distal tip 38 can include a radiopaque marker to aid in locating the tip 38 during insertion into the patient, and is preferably soft to prevent damage to the patient's vasculature. At the distal end of the shaft 38, a guidewire lumen 40 is attached. This lumen 40 provides a separate lumen, apart from the main aspiration lumen 42 of the catheter 30, for the insertion of the guidewire 26. This guidewire lumen can be as short as 5 cm. As illustrated in FIGURE 7A, during delivery of the aspiration catheter 30, the proximal end of the guidewire 26 is inserted into the distal end of the guidewire lumen 40, and the guidewire lumen 40 is slidably advanced over the guidewire 26. Unlike the over-the-wire catheter 10 described above, only a short segment of the single operator aspiration catheter 30 rides over the guidewire 26, and the guidewire 26 remains in the guidewire lumen 40 and does not enter the aspiration lumen 42 of the aspiration catheter 30. With the single operator system 30, the long guidewire 26 used with the over-the-wire catheter 10, and the extra operator needed to handle it, are not required.

Although the guidewire lumen 40 is shown in FIGURE 5 as being located only on the distal end 38 of the shaft of the aspiration catheter 36, the lumen 40 can also be made to extend the entire length of the shaft 36 if desired. In both embodiments, the aspiration lumen 42 is advantageously left completely unobstructed to provide more efficient aspiration. The guidewire lumen 40 can also include a slit in the outside wall of the lumen to facilitate faster and easier insertion and removal of the guidewire 26 through the side wall of the lumen, as shown in FIGURE 7B.

In another embodiment not shown, the aspiration catheter can be configured such that the therapy catheter can be inserted through the lumen of the aspiration catheter. The aspiration lumen is made large enough to accommodate the desired therapy catheter. This allows the aspiration catheter and the therapy catheter to be delivered into the patient at the same time. When therapy is complete, the therapy catheter is removed while the aspiration catheter remains in place. This eliminates the need to separately deliver the aspiration catheter after removal of the therapy catheter, saving valuable time. It is preferable that the size of the guide catheter used during this type of procedure be sized from at least 8 to about 10 French to accommodate the size of the "over-the-therapy-catheter" aspiration catheter.

In yet another embodiment, also not shown, the therapy catheter can be built over the aspiration catheter. For example, a dual-lumen catheter having a dilatation balloon at its distal end can be used. One lumen is used to

inflate the dilatation balloon to be used for angioplasty, while the second lumen is used for aspiration. This design allows a single combined aspiration catheter and therapy catheter to be delivered into the patient. When therapy is complete, aspiration is carried out without the need to first remove the therapy catheter.

In the embodiment where the catheter is adapted to allow aspiration therethrough, no separate aspiration catheter is required. Once the occlusive device on the catheter is positioned distal to the occlusion, the occlusive device is activated to at least partially occlude the vessel. A therapy catheter is delivered and therapy performed on the occlusion. Once therapy is complete, a source of negative pressure is provided at the proximal end of the catheter, and aspiration occurs through the openings at the distal end of the catheter, just proximal to the occlusive device. Aspiration is therefore accomplished without the need for a separate aspiration catheter, or removal of the therapy catheter.

FIGURES 8A, 8B, and 8C illustrate various embodiments of the distal end of the aspiration catheter of the present invention. FIGURE 8A shows the preferred tip 44, wherein the end has been angled. This tip 44 is also shown in FIGURE 5. This angled tip 44 maximizes the area of aspiration. The distal tip of the aspiration catheter can also be blunt 45, as shown in FIGURE 8B, or can be tapered 46, with holes along the tip 47 to provide for aspiration, as illustrated in FIGURES 8C and 2.

Use of the devices just described will now be explained in connection with the method of the present invention.

Method of the Present Invention

The method of the present invention as used to remove plaque and any associated thrombi from a saphenous vein graft is described below in connection with FIGURE 9. Again, it should be noted that this application is merely exemplary, and that the method of the present invention can be used in other blood vessels and to remove other types of occlusions as well.

A guide catheter (not shown) is introduced into the patient's vasculature through an incision in the femoral artery in the groin of the patient. The guide catheter has a single large lumen, and is used to guide the insertion of other catheters and devices. The guide catheter is advanced until it reaches the aorta and the ostium of the vein graft, where it will remain in place throughout the procedure. Fluoroscopy is typically used to guide the guide catheter and other devices to the desired location within the patient. The devices are frequently marked with radiopaque markings to facilitate visualization of the insertion and positioning of the devices within the patient's vasculature.

Next, an occlusive device is delivered to a site distal the occlusion. For example, a catheter or guidewire 50 having an occlusive device at its distal end is delivered through the guide catheter into the saphenous vein graft 5 and past the site of the occlusion 56. In this example, the occlusive device is an inflatable balloon 52. The balloon 52 is inflated to occlude the vein graft 5 at a site distal to the occlusion 56 to create a working area surrounding the occlusion. By "working area" is meant an area extending from the occlusive device is a proximal direction for a distance up to about 20 cm. The blood coming from the aorta enters the saphenous vein graft 5 and keeps any particles 58 dislodged during the procedure from flowing proximally. In addition, the blood pressure and

flow coming from the aorta provides the irrigation necessary for aspiration. As noted above, the blood pressure in the vessel is preferably at least about 0.2 psi, and the flow rate is at least about 10 cc per minute.

Once the vein 5 is occluded, a therapy catheter (not shown) is delivered, if desired. The therapy catheter can be any of a number of devices, including a balloon catheter used to perform angioplasty, a catheter which delivers a stent, a catheter for delivering enzymes, chemicals, or drugs to dissolve and treat the occlusion, an atherectomy device, or a laser or ultrasound device used to ablate the occlusion. Alternatively, the therapy catheter can be eliminated and use of the guide catheter or a separate aspiration catheter alone can be used to aspirate the occlusion. This method is especially useful to remove emboli from the coronary arteries following acute myocardial infarction, because the aspiration catheter can be made small enough to enter the coronary arteries.

Once the desired therapy is performed, the therapy catheter is withdrawn from the patient's body and an aspiration catheter 60 is delivered over the guidewire 50 and through the guiding catheter. The aspiration catheter 60 rides over the guidewire 50 with the guidewire 50 inserted through the aspiration lumen 62 of the catheter 60. Alternatively, a single operator type aspiration catheter can be used, in which only a portion of the aspiration catheter rides over the guidewire, which is inserted into a separate guidewire lumen. FIGURE 9 illustrates the treatment site after the over-the-wire aspiration catheter 60 is inserted into the saphenous vein graft 5.

It is important that the distal tip of the aspiration catheter 64 be initially positioned as close to the occlusive balloon 52 as possible, preferably less than about 5 cm from the proximal side of the balloon 52. The operator then slides the aspiration catheter in a proximal direction, increasing the distance between the distal tip 64 and the balloon 52. Aspiration can therefore occur anywhere between about 0 to 20 cm proximal to the occlusive device. If desired, the distal tip of the aspiration catheter 64 can be slidably advanced in the distal direction more than once to ensure complete aspiration of all debris. The blood pressure supplied by the aorta will move any particles 58 from a position proximal to the distal tip of the aspiration catheter 64, thus allowing them to be aspirated, as illustrated by the arrows in FIGURE 9. If a particle, however, is too far distal to the tip of the aspiration catheter 64, the blood pressure will keep it there and not allow it to aspirated from the vessel 5. Once aspiration has begun, additional blood will flow into the area, creating turbulence and allowing for the complete removal of debris.

A preferred source of negative pressure is any rigid container containing a fixed vacuum, such as a syringe, attached to the proximal end of the aspiration catheter at the aspiration port 34 (see FIGURE 5). A mechanical pump or bulb or any other appropriate source of negative pressure can also be used. The difference between the existing pressure within the vessel and the aspiration pressure within the vessel should not exceed about 50 psi. If too much aspiration pressure is applied, the change in pressure in the vessel will be too great and damage may occur to the vessel itself.

After the area inside the graft 5 just proximal to the occlusive balloon 52 is aspirated to remove any particles 58 or other debris, the aspiration catheter 60 is removed. The balloon 52 is deflated and the guidewire 50 and guiding catheter are removed.

As described above, the aspiration catheter can be sized such that it can receive the therapy catheter within its lumen or the therapy catheter can be built over the aspiration catheter. In either case, the aspiration catheter and the therapy catheter are delivered over the guidewire and into the vein graft together. When therapy is complete, the therapy catheter can be removed while the aspiration catheter remains in place. When aspiration is complete, the aspiration catheter, guidewire and guiding catheter are removed from the patient's body. Delivering the aspiration catheter and therapy catheter together saves time, which is critical during these types of procedures. Alternatively, the guide catheter can be used to provide aspiration through its main lumen.

In yet another embodiment, aspiration takes place through the lumen of the catheter or guidewire. The occlusive device on the catheter is positioned distal to the occlusion, and the occlusive device is activated to at least partially occlude the vessel. The therapy catheter is delivered and therapy performed. A source of negative pressure is provided at the proximal end of the catheter, and aspiration occurs through openings located at the distal end of the catheter just proximal to the occlusive device. This eliminates the need for a separate aspiration catheter, and the need to remove the therapy catheter prior to aspiration. Again, this saves time, which is critical during these types of procedures.

In yet another aspect as shown in Figure 9, there is provided a method of performing a diagnostic procedure in which the preferred intravascular catheters, described herein are utilized to remove emboli, thrombus, and other obstructions from the vessel of a patient, such as an SVG graft, in order to determine the nature of such obstruction. For example, if the analysis (which may be performed visually or laboratorially) of the aspirated or otherwise removed obstruction indicates that it is in the nature of a thrombus or similar blood clot, then the patient may be treated with suitable anti-clotting medication. On the other hand, if the aspirated obstruction is in the nature of an embolus, which may comprise plaque, then the patient may be treated with suitable anti-cholesterol medication. In addition, as a result of such a diagnostic procedure, the stenosis or other lesion which produced such plaque may be irradiated in order to decrease the risk of reoccurrence. Thus, there is provided this preferred diagnostic method in which an intravascular aspiration system is used to remove obstructions from the vasculature of a patient for further analysis.

WHAT IS CLAIMED IS:

1. A kit comprising a plurality of catheters in combination for use in the removal of occlusions from blood vessels, characterized in that the plurality of catheters comprises:

a catheter bearing an occlusive device;

a therapy catheter; and

an aspiration catheter.

2. The kit of Claim 1, further characterized in that each of said catheters is capable of independent manipulation within the blood vessels.

3. The kit of either Claim 1 or 2, for use in saphenous vein grafts.

4. The kit of either Claim 1 or 2, further characterized in that the catheter bearing an occlusive device comprises an elongated tubular body, an inflatable balloon mounted on a distal end the tubular body, a core-wire joined to the distal end of the tubular body, and a coil member disposed about the core-wire.

5. The kit of any of Claims 1-2, further characterized in that the aspiration catheter comprises an elongate hollow shaft, a distal tip adapted for aspiration therethrough, and a proximal end adapted for connection with a source of negative pressure.

6. A method for the treatment of an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, comprising:

inserting a first catheter having an occlusive device on its distal end into said blood vessel, until said occlusive device is distal to said occlusion;

activating said occlusive device to occlude said vessel distal to said occlusion and create a working area surrounding said occlusion;

inserting a therapy catheter into said blood vessel until it reaches said occlusion;

performing therapy on said occlusion;

allowing said fluid pressure within said vessel to prevent any particles produced during said therapy from flowing against said pressure and out of said working area;

removing said therapy catheter;

aspirating fluid from said working area inside the vessel proximal to the occlusive device to remove said particles while allowing said fluid pressure to provide irrigation fluid within said working area; and

deactivating said occlusive device and removing said catheter.

7. The method of Claim 6, further comprising the step of inserting a distal end of a debris removal device into said working area to a position just proximal to said occlusive device following the removal of said therapy catheter and aspirating fluid through said debris removal device.

8. The method of Claim 7, wherein said debris removal device comprises an aspiration catheter.

9. The method of Claim 6, wherein said first catheter comprises a guidewire.

10. The method of Claim 9, wherein said aspiration catheter comprises a hollow lumen, and wherein said inserting step comprises inserting a proximal end of said first catheter into said hollow lumen and slidably advancing said aspiration catheter over said first catheter.

11. The method of Claim 9, wherein said aspiration catheter comprises a hollow lumen and a separate first catheter lumen, and wherein said inserting step comprises inserting a proximal end of first catheter into said first catheter lumen and slidably advancing said first catheter lumen over said first catheter.

12. The method of Claim 9, wherein said distal end of said aspiration catheter is inserted at least one time to a position no more than about 5 cm proximal to said occlusive device and thereafter slidably withdrawn in a proximal direction.

13. The method of Claim 6, wherein said blood vessel is selected from the group consisting of a saphenous vein graft, a coronary artery, and a vessel above the aortic arch.

14. The method of Claim 6, wherein said blood vessel has a fluid flow rate of at least about 10 cc per minute.

15. The method of Claim 6, wherein said blood vessel has a fluid flow rate of from about 60 to about 80 cc per minute.

16. The method of Claim 6, further comprising the first step of inserting a guide catheter to aid in the insertion of said occlusive device and said catheters.

17. The method of Claim 16, wherein said aspirating step is performed using said guide catheter.

18. The method of Claim 6, wherein activating step results in the vessel being substantially occluded.

19. The method of Claim 6, wherein said occlusive device is a balloon and said activating step comprises inflating said balloon.

20. The method of Claim 6, wherein said occlusive device is a filter and said activating step comprises deploying said filter to prevent migration of particles downstream.

21. The method of Claim 6, wherein said performing step comprises delivering a drug directly to the site of said occlusion.

22. The method of Claim 6, wherein said performing step comprises creating a venturi effect within said vessel to aspirate said occlusion, and wherein said aspirating step occurs simultaneously.

23. The method of Claim 6, wherein said performing step comprises creating turbulence within said vessel, and wherein said aspirating step occurs simultaneously.

24. The method of Claim 6, wherein said therapy catheter is selected from the group consisting of a thrombectomy catheter, a rheolitic device, and a device which creates a venturi effect within the vessel, and wherein said performing and said aspirating steps are performed simultaneously.

25. The method of Claim 6, wherein said aspirating step is performed using said first catheter.

26. The method of Claim 6, wherein said inserting step comprises simultaneously inserting the therapy catheter and a debris removal device into said blood vessel until they reach said occlusion, and said removing step is performed following said aspirating step.

27. The method of Claim 6, wherein said catheter comprises a guidewire.

28. The method of Claim 26, wherein at least a portion of said debris removal device or said therapy catheter is slidably advanced over said catheter during said delivery step.

29. The method of Claim 26, further comprising the step of inserting said therapy catheter into a lumen of said debris removal device prior to said inserting step.

30. The method of Claim 29, further comprising the step of removing said therapy catheter prior to said aspirating step.

31. The method of Claim 26, wherein said therapy catheter and said debris removal device comprise a single catheter.

32. The method of Claim 31, wherein said single catheter comprises an aspiration lumen and an inflatable balloon on a distal end.

33. A method for the removal of an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, comprising:

inserting an occlusive device into said vessel, until said occlusive device is distal to said occlusion;

activating said occlusive device to at least partially occlude said vessel distal said occlusion and create a working area surrounding said occlusion;

allowing said fluid pressure within said vessel to prevent any particles dislodged during insertion of said catheter from flowing against said pressure and out of said working area;

inserting a distal end of a debris removal device to a position just proximal to said occlusive device;

aspirating fluid from said working area inside the vessel just proximal to the occlusive device to aspirate said occlusion and said particles while allowing said fluid pressure to provide irrigation fluid within said area;

removing said debris removal device; and

deactivating said occlusive device and removing it.

34. The method of Claim 33, wherein said distal end of said debris removal device in inserted at least one time to a position no more than about 5 cm proximal said occlusive device.

35. The method of Claim 33, wherein said vessel has a flow rate of at least about 10 cc per minute.

36. The method of Claim 33, wherein said vessel is a coronary artery.

37. The method of Claim 33, wherein said debris removal device comprises a guide catheter.

38. The method of Claim 33, wherein said debris removal device comprises an aspiration catheter.

39. The method of Claim 33, wherein said occlusive device is mounted on a distal end of a catheter.

40. The method of Claim 39, wherein said occlusive device is a balloon and said activating step comprises inflating said balloon.

41. The method of Claim 33, wherein said occlusive device is a filter and said activating step comprises deploying said filter to prevent migration of particles downstream.

42. The method of Claim 33, wherein said debris removal device is selected from the group consisting of a rheolitic device, a thrombectomy catheter, and a device which creates a venturi effect within the vessel.

43. A method of performing a diagnostic procedure in an SVG graft or other vessel of a patient, comprising the steps of removing thrombus, emboli, or other obstructions from the vasculature of the patient and analyzing such articles to determine subsequent patient treatment.

44. The method of Claim 43, wherein said diagnostic procedure is performed utilizing the catheter kit of Claim 1.

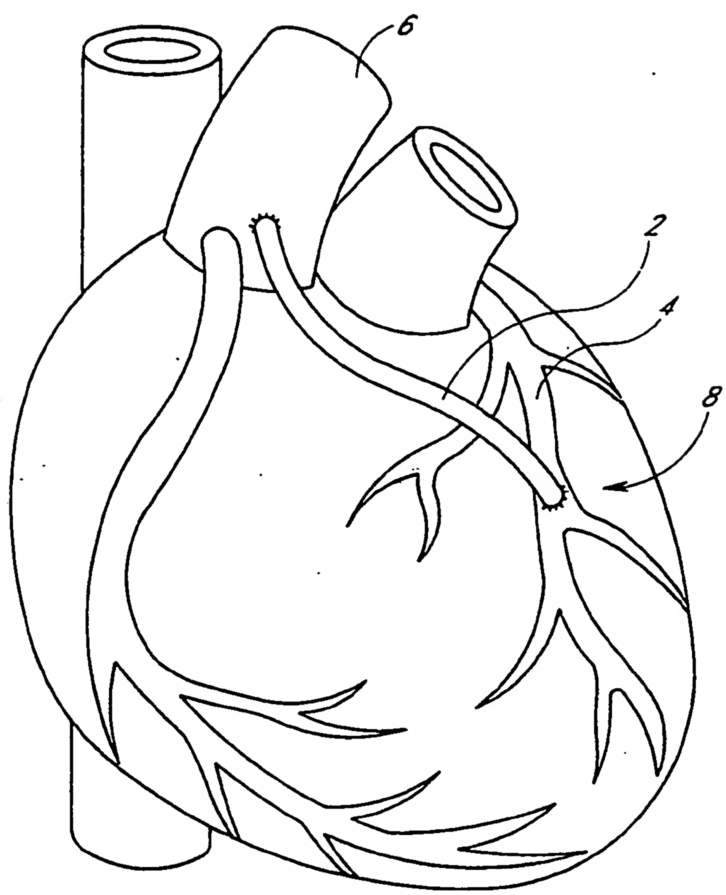


FIG. 1

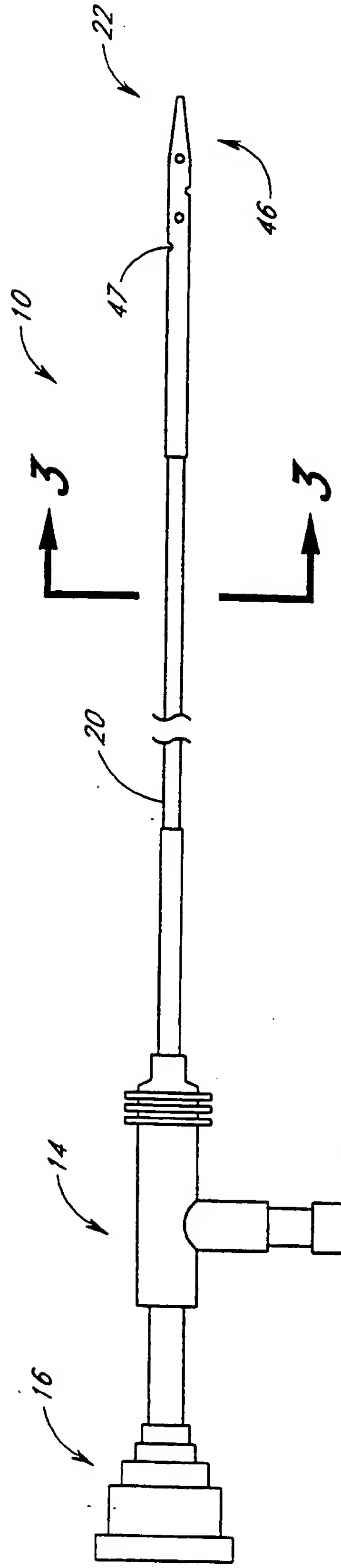


FIG.2

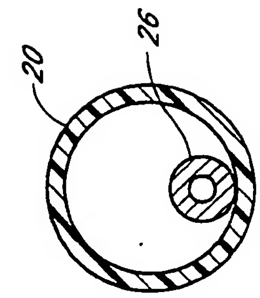


FIG.4

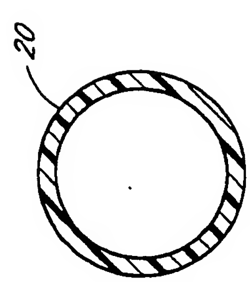


FIG.3

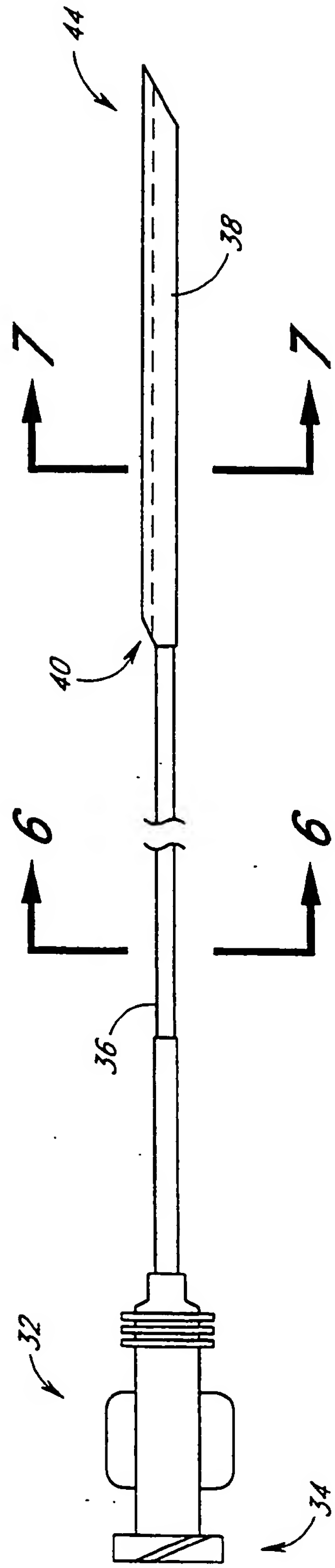


FIG.5

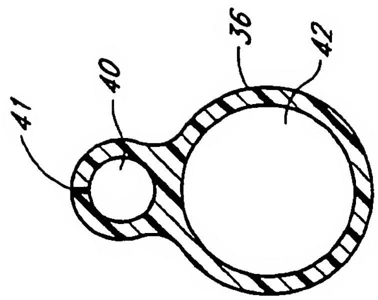


FIG.7B

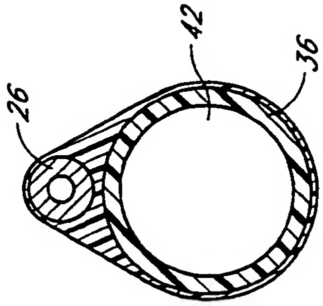


FIG.7A

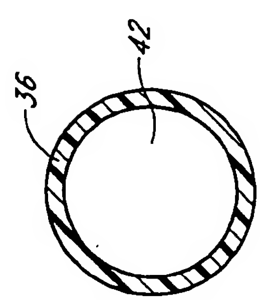


FIG.6

FIG.8A

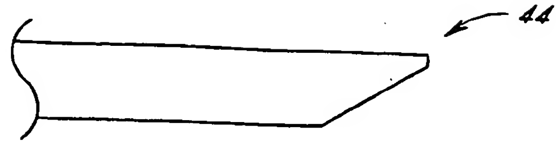


FIG.8B

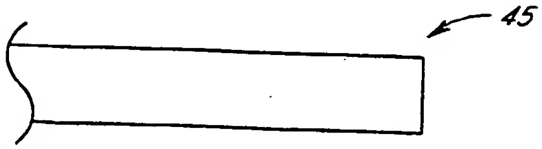
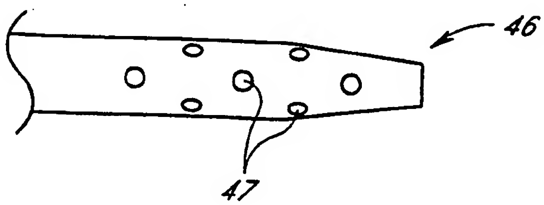


FIG.8C



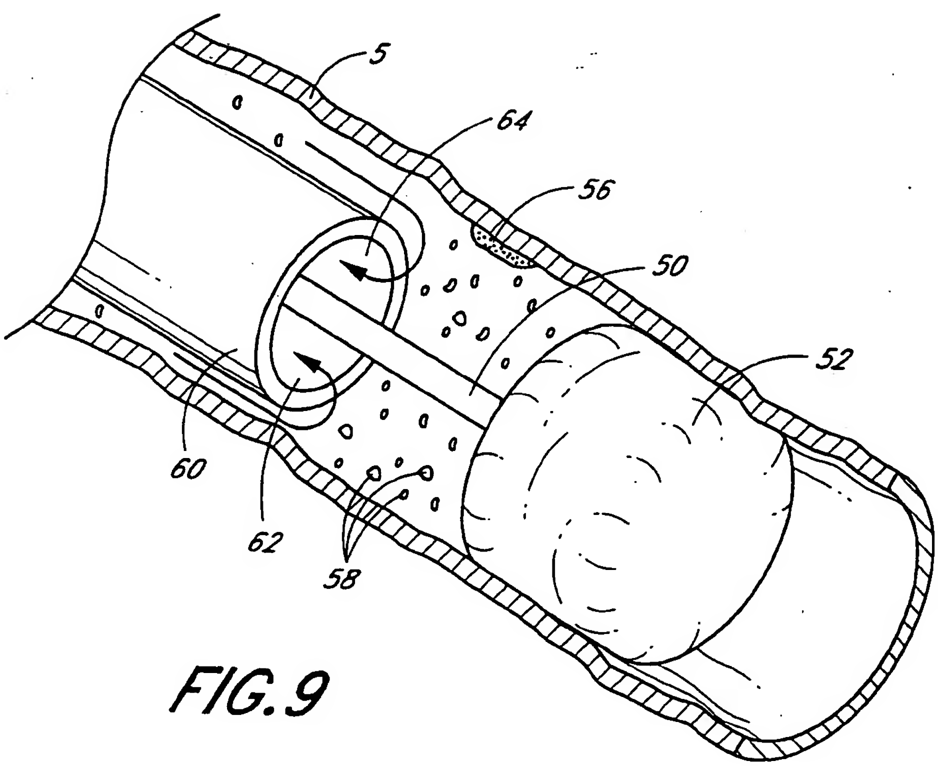


FIG.9

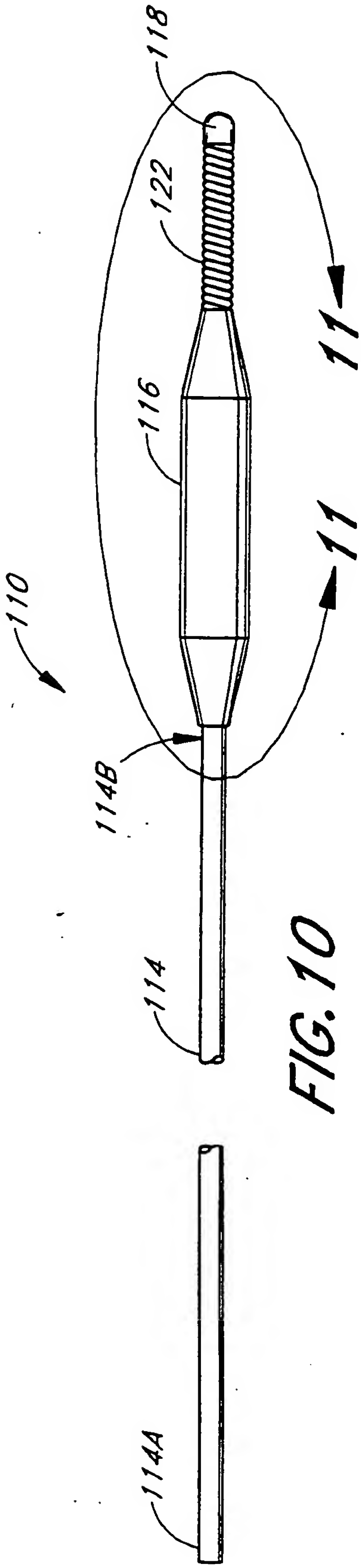

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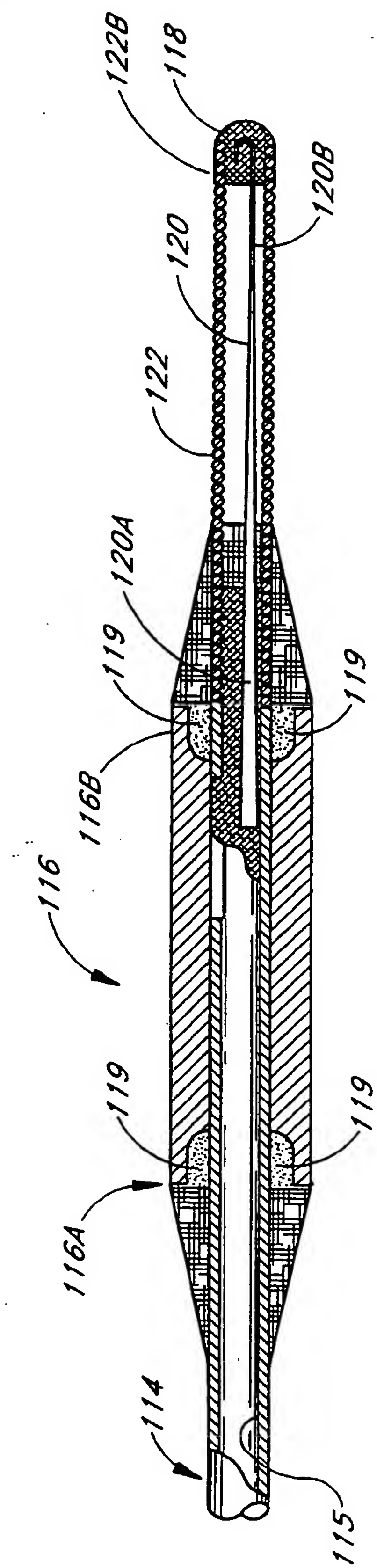
FIG. 10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116B
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116A
114
115

FIG. 11

INTERNATIONAL SEARCH REPORT

Inter   onal Application No
PCT/US 98/04366

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 5 681 336 A (AUTH DAVID C ET AL) 28 October 1997 see the whole document ---	1-5
X A	WO 95 09024 A (TECHNOLOGY DEV CENTER) 6 April 1995 see the whole document ---	1-3,5 4
X A	US 5 059 178 A (YA WANG D) 22 October 1991 see the whole document ---	1,2,5 4
A	WO 96 01079 A (SCIMED LIFE SYSTEMS INC) 18 January 1996 see page 1, line 11 - page 3, line 2 see abstract; figure 1A ---	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 1998	24.07.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, P

1

INTERNATIONAL SEARCH REPORT

Inte   onal Application No
PCT/US 98/04366

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 964 409 A (TREMULIS WILLIAM S) 23 October 1990 see abstract; figure 1 -----	4

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/04366

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6-44
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .onal Application No
PCT/US 98/04366

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5681336	A	28-10-1997	NONE		
WO 9509024	A	06-04-1995	US	5462529 A	31-10-1995
			AU	7846694 A	18-04-1995
US 5059178	A	22-10-1991	JP	1752627 C	08-04-1993
			JP	2055064 A	23-02-1990
			JP	4038435 B	24-06-1992
WO 9601079	A	18-01-1996	US	5536242 A	16-07-1996
US 4964409	A	23-10-1990	US	4953553 A	04-09-1990
			US	5050606 A	24-09-1991
			CA	2016339 A	11-11-1990
			EP	0397173 A	14-11-1990
			JP	3090166 A	16-04-1991
			US	5159937 A	03-11-1992